**Scale Loss Score (SLoS): a novel measure of drug benefit-risk assessment**

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**Introduction**

- **MultiCriteria Decision Analysis (MCDA)** is a popular quantitative method to assess the benefit-risk (BR) balance of treatments: it permits to summarize the benefits and the risks of a drug in a single utility score.

- The utility score is often derived using a linear model which might lead to counter-intuitive conclusions, for example, a recommendation of a non-effective drug.

- We propose Scale Loss Score (SLoS) as a new tool for benefit-risk assessment: it is based on strong theoretical principles, addresses the issues of the linear MCDA model and can lead to more meaningful recommendations.

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**Notations**

- \(\xi_j\): performance of treatment \(i\) on criterion \(j\), \(j = 1, \ldots, n\)
- \(u_j(\xi_j)\): linear partial value functions - map the performances on criterion \(j\) to a \((0, 1)\) scale
- \(u_j(\xi_j) = \frac{\xi''_j - \xi'_j}{\xi''_j - \xi'_j}\): the worst and best values
- \(w_j\) and \(\tilde{w}_j\): weight reflecting the importance of criterion \(j\)

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**Examples**

**Fictive examples**

<table>
<thead>
<tr>
<th>Drug 1</th>
<th>Drug 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit</td>
<td>0%</td>
</tr>
<tr>
<td>Risk</td>
<td>9%</td>
</tr>
<tr>
<td>MCDA</td>
<td>0.6825</td>
</tr>
<tr>
<td>SLoS</td>
<td>+∞</td>
</tr>
</tbody>
</table>

\(\rightarrow\) SLoS strongly penalizes extremely low benefit values and extremely high risk values.

**Case study: telithromycin**

- IMI PROTECT Benefit-Risk Group example
- \(\text{Prob}(\text{telithromycin} > \beta\text{-lactam antibiotics})\)

<table>
<thead>
<tr>
<th>Community Acquired Acute Bacterial Pneumonia (CAP)</th>
<th>Sinusitis (ABS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCDA</td>
<td>59%</td>
</tr>
<tr>
<td>SLoS</td>
<td>51%</td>
</tr>
</tbody>
</table>

\(\rightarrow\) SLoS results are more in line with the regulatory authorities concerns on ABS indication (CHMP reassessment and FDA removal)

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**Conclusion**

**Results of simulations comparing MCDA and SLoS:**

- Both are robust to correlations between outcomes.

- Similar conclusions in many cases.

- Clear advantage of SLoS when drugs have no benefit or extreme risk.

**Scale Loss Score (SLoS) is a novel, simple and valuable tool for BR assessment.**